REMARKS

Independent Claim 1 has been amended to clarify the invention and better distinguish the invention from the prior art. No new matter has been entered. Support is found, for example, in the paragraph bridging pages 10-11 of the original specification.

Before considering the latest art rejections, a brief review of the prior art and the present invention may be helpful to the Examiner. Certain diseases of the respiratory tract are known to respond to treatment by the inhalation of therapeutic agents. As these agents are most readily available in dry powdered form, their application is most conveniently accomplished by inhaling the powdered material through the nose or mouth. This powdered form results in the better utilization of the medication particularly when the drug is deposited deeply into the lungs. Hence, minute doses of the drug are often equally as efficacious as larger doses administered by other means, with a consequent marked reduction in the incidence of undesired side effects and medication cost. However, deep delivery into the lungs requires relatively small particle sizes. Too large particles may be deposited in the mouth or throat where the drugs may not be absorbed, or systemic absorption may be less than optimal.

Prior art dry powder inhalers usually have a means for introducing the drug (active drug plus carrier) into a high velocity air stream. The high velocity air-stream is used as the primary mechanism for breaking up the cluster of micronized particles or separating the drug particles from the carrier. Several inhalation devices useful for dispensing this powder form of medication are known in the prior art. These devices also may have a means for puncturing or removing the top of a capsule containing a powdered medication, which upon inhalation is

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drawn out of the pierced or topped capsule and into the user's mouth using, e.g., the user's inhalation aided by a propeller means.

The prior art devices have a number of disadvantages which make them less than desirable for the delivery of dry powder to the lungs. Some of these disadvantages are:

- The performance of the prior art inhalers depends on the flow rate generated by the user. Lower flow rate does not result in the powder being totally de-aggregated and hence adversely affects the dose delivered to the patient;
- Inconsistency in the bioavailability of the drugs from dose-to-dose because of lack of consistency in the de-aggregation process;
- Large energy requirements for driving the electromechanical based inhalers which increases the size of the devices making them unsuitable for portable use;
- Loss of medication from opened or topped capsules; and
- Deterioration of medication in open or topped capsules due to exposure to oxygen or moisture.

In accordance with the present invention, controlled aliquots or doses of a medication or drug are pre-packaged in a flexible coiled tape blister pack. The blister pack includes a frangible crowned top element which may be conical, conical with a rounded point, rounded, or other raised shape configuration, and a bottom element which may be a flat web or membrane, or which itself may be of shaped configuration, e.g. conical, round, dish shaped, etc. (Specification pg. 10, lines 5-12)

In use, the bottom of the blister pack is coupled to the vibratory de-aggregator prior to or contemporaneously with piercing a top element with a piercing device such as a sharp needle or needles. The holes thereby created form one or more apertures for enabling the release of

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the medication or drug contained within the blister pack. Activation of the vibratory de-aggregator drives the medication or drug from the blister pack through the holes in the top element into the inhalation device. (Specification pg. 10, lines 13; pg. 11, lines 2-5).

The hole pattern and hole size of the apertures created in the top element provide optimization of delivery of the particular medication or drug packaged therein. The holes also act as filters, preventing the ejection of oversize, i.e. aggregated or agglomerated particles from the blisters, until the particles are broken up to optimal size by energy input from the vibratory de-aggregator. Thus, in the case, e.g. of a dry powder medication or drug or a liquid medication or drug, particle size and dose of the medication or drug delivered can be optimized, and tailored to the frequency of the vibratory de-aggregator. (Specification pg. 10, lines 14-21; pg. 11, lines 1 & 2).

None of these features are taught or suggested by Abrams or any of the secondary references applied by the Examiner.

Considering first the rejection of claims 1, 3, 8 and 13-15 is obvious from Abrams et al. in view of Casper et al., in the primary reference Abrams et al., the film covering the blisters or wells holding the drug is peeled back to expose the blisters or wells carrying the drug. (Column 5 lines 33-43). Thus, there is no top layer of film being punctured, and no puncture holes formed which could act as filters to prevent ejection of oversize particles as required by claim 1, as amended. Moreover, this distinction is more than merely academic. If you take away the top film layer taught by Abrams, you can't form puncture holes which can act as a filter. Thus, with Abrams et al., it is not possible to control particle size, etc.

Moreover, maintaining the top of the blister substantially intact with only puncture holes provides other advantages. With Applicant's claimed invention, the drug contained

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within a blister pack would still be protected from contamination or moisture even after the puncture holes are formed. Moreover, Applicant's claimed invention is not position sensitive. Thus, by maintaining the top crowned blister intact (other than the puncture holes), Applicant can deliver multiple doses from a single blister, or deliver a single dose in small aliquots over an extended time period.

Casper et al. does not supply the missing teachings to Abrams et al. to achieve render obvious of claim 1. Casper et al. teaches driving a single puncture tool or lancet 56 completely through a medicament filled blister 42, i.e. through both the top and bottom elements forming the blister. In Casper et al., the medicament may then be drawn from the punctured blister by gravity and vacuum. There is no attempt by Casper et al., no teaching or suggestion within the four corners of Casper et al. of a vibrator, or of controlling particle size by breaking up the particles by vibration, and filtering the particles through the puncture holes. Thus, no combination of Abrams et al. and Casper et al. reasonably could be said to achieve or render obvious independent claim 1, as amended.

Claim 3, 8 and 13-15 are all directly dependant on claim 1. The deficiencies of the combination of Abrams et al. and Casper et al. vis-à-vis claim 1 are discussed above. Claims 3, 8 and 13-15 are patentable over Abrams et al. and Casper et al. for the same reasons above adduced relative to claim 1 as well as for their own additional limitations.

Turning to the rejection of claim 9 as obvious from Abrams et al. in view of Pera, claim 9 is dependant on claim 1. The deficiencies of the primary reference Abrams et al. vis-à-vis claim 1 are discussed above. Pera does not supply the missing teachings to Abrams et al. to achieve or render obvious claim 1 or claim 9. Pera has been cited as teaching dispensing an antioxidant vitamin by inhalation. However, Pera nowhere teaches or suggests any structure.

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Thus, the structural deficiencies of Abrams et al. discussed above clearly are not supplied by Pera. Accordingly, no combination of Abrams et al. and Pera can be said to achieve or render obvious claim 1 or claim 9 which depends thereon, and, the rejection of claim 9 as obvious from Abrams et al. in view of Pera is in error.

The rejection of claims 10 and 11 as obvious from Abrams et al. in view of Hendricks is likewise an error. Claims 10 and 11 are dependent on claim 1. The deficiencies of the primary reference Abrams et al. vis-à-vis claim 1 are discussed above. It is not seen that Hendricks supplies the missing teachings to Abrams et al. to achieve or render obvious claim 1 or claims 10 and 11 which depend thereon. Hendricks has been cited as teaching a dry powder inhaler in which the material comprises a hormone or steroid. However, Hendricks' inhaler is radically different in construction from Abrams et al. Nowhere is there any teaching or suggestion within Hendricks as to how the Abrams et al. inhaler should be modified, i.e., to form a flexible coiled tape blister pack having a top spaced crowned area formed of a frangible element through which puncture holes are formed and act as filters to prevent the ejection of over sized particles of the material as required by Applicant's claims. Accordingly, no combination of Abrams et al. and Hendricks can achieve or render obvious claim 1 or claims 10 and 11 which depend thereon, and, the rejection of claims 10 and 11 as obvious from Abrams et al. in view of Hendricks also is in error.

The rejection of claim 12 is obvious from Abrams et al. in view of Shyjan likewise is in error. Claim 12 is dependent on claim 1. The deficiencies of the primary reference Abrams et al. are discussed above. It is not seen that Shyjan supplies the missing teachings to Abrams et al. to achieve or render obvious claim 1 or claim 12 which depends thereon. Shyjan has been cited as teaching a bioactive material. However, Shyjan, like Pera contains absolutely no

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teaching or disclosure of inhaler structure or any form of blister back for use with an inhaler structure. Thus, no combination of Abrams et al. and Shyjan could be said to achieve or render obvious claim 1 or claim 12 which depends thereon. Accordingly, the rejection of claim 12 as obvious from Abrams et al. in view of Shyjan also is in error.

Having dealt with all the objections raised by the Examiner, the Application is believed to be in order for allowance.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account Number 08-1391.

Respectfully submitted,

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